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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,108

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EXAMINER

HEYER, DENNIS

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,108	Applicant(s) NIELSEN ET AL.	
	Examiner DENNIS HEYER	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/16/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-31 is/are rejected.
- 7) ☒ Claim(s) 11-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 16, 2010 has been entered.

Acknowledgement is made of Applicant's remarks and amendments filed August 16, 2010. Acknowledgement is made of the addition of new claims 22 – 31 and the amendment to independent Claims 11 and 20 which now include the limitation 'curing said hydrophilic polymer "without rewetting the medical device"'.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant's arguments with respect to Claim 11 – 21 have been considered but are moot in view of the new ground(s) of rejection. The previously applied rejections of Claims 11 – 21 under U.S.C 103(a) (Madsen in view of Hunter and Madsen in view of Hunter and further in view of Larsen) are withdrawn because following the procedure of

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Madsen would involve rewetting the medical device, which is now excluded by the claim amendment.

Status of Claims

Claims 11 – 31 are currently pending

Claim rejections - 35 USC § 112 - 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 – 17 is rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "wherein said curing is the only irradiation step in the process" in Claim 11 is indefinite because it is unclear whether curing requires irradiation, or whether curing can be carried out by another process which does not require irradiation and, therefore, there is no irradiation step in the process. Because the term "wherein said curing is the only irradiation step in the process" can be construed in two ways, i.e. irradiation is either required, or not required; the metes and bounds of the claim are unclear and the claim is indefinite.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 – 13, 15 – 24 and 26 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard in WO 89/09246 (published: October 5, 1989; IDS dated 3/8/2010, Foreign Patent Document Cite No. AM) in view of Hunter *et al.* in US 2004/0043052 (filed: May 27, 2003; previously applied in the Office Action mailed 5/14/2010).

Howard teaches solid shaped structures having a surface coated with a crosslinked hydrophilic polymer and a process for preparing said structures, the coating being durable and exhibiting a low coefficient of friction when wet (Abstract). The

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coating process is carried out by: 1) contacting (applying or dipping) a solid surface with a solution of crosslinkable hydrophilic polymer and optionally, a free radical initiator (an additive), 2) drying the coated surface and, 3) crosslinking (curing) the hydrophilic polymer of the dried coated surface (page 4, lines 18 – 34).

Crosslinking is carried out by exposing the dried coated surface to either heat, UV radiation in the presence of a free radical initiator or, subjecting it to electron beam radiation in the absence of additives (page 4, lines 1 – 15; page 6, lines 4 – 10).

Howard teaches solvents suitable for dissolving the hydrophilic polymer include water, methylene chloride, ethanol, etc. (page 8, lines 5 – 14). Accordingly, the polymer solution which is applied to the solid surface of Howard comprises at least one solvent (instant Claims 13 and 24). The curing (crosslinking) step of Howard does not require rewetting the dried coated surface as recited in amended Claims 11 and 20. As noted above, the method of Howard only requires a single application (dipping) step (see also Examples 1 – 11; instant Claims 12 and 23). Howard teaches the preferred hydrophilic polymer is polyvinylpyrrolidone (PVP) (page 20, lines 18 – 20; instant Claims 16, 21, 27 and 31) and is present in the solution applied to the surface to be coated at ~ 3 weight percent (Examples 1 – 9; instant Claims 11, 20, 22 and 30).

Howard teaches the coatings are suitable for medical application, for example, catheters, scopes, tubes and wound dressings (i.e. medical devices; pages 11 – 12, bridging paragraph). Howard teaches, in Example 9, a method for coating a polyurethane catheter, the method steps consisting of dipping a polyurethane catheter tube (i.e. providing a medical device with a substrate polymer surface) into a methylene

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chloride solution (i.e. providing a solution (a vehicle) and applying said solution to the catheter substrate polymer surface) containing 3 weight percent polyvinylpyrrolidone (PVP) and 1 weight percent benzoyl peroxide (an additive); drying overnight (i.e. evaporating at least a part of the solution (vehicle) on the polymer surface); and crosslinking the at least partially dried coated surface by heating 1 hour in air at 110 °C (i.e. curing the hydrophilic polymer).

It is noted that Howard teaches the crosslinked coating prepared in Example 9 is subsequently washed in water and then tested for coefficient of friction. Such a 'step' (subsequent washing) is not recited in Claim 22 which consists of only the applying, drying and crosslinking steps. However, Howard teaches that subsequent washing in water at physiological temperature is carried out only to determine the durability of the crosslinked coating prior to testing its coefficient of friction and is therefore not a process step in preparing said coating (see page 9, lines 13 – 20).

Howard teaches the process of coating a medical device (a catheter) by applying a catheter to a solution containing 3 weight % of the hydrophilic polymer PVP and an additive (benzoyl peroxide). However, the coating solutions of Howard do not contain a plasticizer as required in the method Claims 11, 20 and 30, and the coated medical device product Claims 17 – 19 and 28 – 29.

Hunter teaches compositions and methods for coating medical implants (Title) and, further, teaches polymer coatings comprising triethyl citrate as a plasticizer in order to increase the flexibility of the coating (p [0095], [0109]). Hunter is silent on the physical properties of triethyl citrate recited in the instant Claims. However, as

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evidenced by Table 1 (page 10) of the present specification, triethyl citrate has the properties recited in instant Claims 11, 18 - 20, 22, 29 and 30 (i.e. solubility in water of at least 6 g/L, a boiling point above 210°C at 760 mmHg, and a Hansen δ_H parameter of less than 20).

It would have been *prima facie* obvious to one of ordinary skill in the art to modify the polymer solution in the coating method of Howard to include the plasticizer triethyl citrate. One would have been motivated to do so with a reasonable expectation of obtaining a coating on a catheter with increased flexibility because Hunter teaches triethyl acetate is a plasticizer recognized in the art to increase the flexibility of medical device coatings.

Claims 14 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard in WO 89/09246 (published: October 5, 1989) and Hunter *et al.* in US 2004/0043052 (filed: May 27, 2003), as applied to Claims 11 – 13, 15 – 24 and 26 – 31 above, and further in view of Larsen *et al.* in US patent 5,484,565 (published January 16, 1996; previously applied in the Office Action mailed 5/14/2010).

Howard in combination with Hunter renders obvious the limitations of instant Claims 11 – 13, 15 – 24 and 26 – 31. With respect to claims 14 and 25, the references discloses that the polymer solution has the ranges claimed for the solution containing the hydrophilic polymer and additives but does not teach the recited % weight range of plasticizer.

Larsen teaches methods for making polymer articles such as catheters which are contacted with a solvent and a plasticizer softer and more pliable or flexible (Abstract).

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Larsen teaches that when the plasticizer is combined with the swelling agent (solvent) the resulting solution preferably contains 50 – 90 % of the solvent and 1 – 50 % of the plasticizer (column 11, lines 14 – 27). The ranges taught by Larsen substantially overlap those recited in instant Claims 14 and 25. See MPEP 2144.05: In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to employ the range of plasticizer (1 – 40 %) and solvent (50 – 90 %) taught by Larsen in the method of Howard and Hunter to prepare a coated catheter. One would have been motivated to do so because these ranges have been taught Larsen to be suited to beneficially modify the flexibility or pliability of a catheter.

Conclusion

Claims 11 – 31 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached at (571)272-2919. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DENNIS HEYER/
Examiner, Art Unit 1628

/Timothy P Thomas/
Examiner, Art Unit 1628